

Amendments to the Drawings:

The attached new sheet of drawings shows new FIG. 42d which has been described in the specification at new paragraph [0075.1] and amended paragraphs [0152] and [0154]. No new matter has been added.

Attachment: New Sheet

REMARKS

Claims 36-45 are currently pending in the present application. In the Office Action mailed November 25, 2005, claims 36-45 were rejected. Applicant respectfully traverses the rejections. Claim 45 has been canceled, without prejudice. Applicant reserves the right to resubmit this claim, or claims of similar scope, in a continuation application. Claim 36 has been amended and no new matter has been added.

Drawing Objection

The drawings were objected to under 37 C.F.R. § 1.83(a). The Examiner has asserted that certain features of the invention have not been shown. The applicant has submitted a new drawing sheet in compliance with 37 C.F.R. § 1.121(d) and believes that the drawings are in compliance with 37 C.F.R. § 1.83(a).

New Matter Objection

The Examiner objected to the amendment filed on September 2, 2005 under 35 U.S.C. § 132(a) and asserted that new matter was introduced into the disclosure.

The Examiner asserted that "there is no discussion of ablating subsequent to sealing the opening in the septum." With respect to the language of claim 36 cited by the Examiner, applicant traverses this rejection and cites paragraph [152] of the specification (as amended) wherein it states

"the present invention may be utilized to sealably traverse the atrial septum 326 and precisely ablate and inject medicament to an isolated chamber 328 of the heart."

Thus, applicant asserts that the specification supports the language of claim 36.

With respect to the claim language of claim 45 cited by the Examiner, the applicant traverses the rejection as a third balloon is inherent in the disclosure which states that a balloon device can be used as a tissue stabilizer (see paragraph [150]). However, in the interests of expediting prosecution the applicant has canceled claim 45

without prejudice to resubmitting the claim, or claims of similar scope, in a continuation application.

Written Description Rejection

Claims 36-38 and 45 were rejected under 35 U.S.C. § 112, first paragraph. The Examiner asserted that these claims fail to comply with the written description requirement.

With respect to claim 36-38, applicant traverses the rejection and reiterates the citation to paragraph [152] of the specification (as amended) referenced in the previous section. The originally filed disclosure is not silent as to the claim language referenced by the Examiner.

With respect to claim 45, the applicant reiterates that a third balloon is inherent in the specification. However, in the interests of expediting prosecution the applicant has canceled claim 45 without prejudice to resubmitting the claim, or claims of similar scope, in a continuation application.

Indefiniteness Rejection

Claims 36-38 and 45 were rejected under 35 U.S.C. § 112, second paragraph. The Examiner asserted that these claims are indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 36 has been amended to provide for antecedent basis for the elements cited by the Examiner and no new matter has been added. In the interests of expediting prosecution the applicant has canceled claim 45 without prejudice to resubmitting the claim, or claims of similar scope, in a continuation application.

Rejection under 35 U.S.C. § 102(e)

Claims 42-44 were rejected under 35 U.S.C. §102(e) as being anticipated by Flaherty et al. Applicant respectfully traverses the rejection.

The Examiner has failed to point out the portion of the disclosure of Flaherty et al. upon which his rejection is based. Applicant believes that the Examiner has misconstrued the reference.

Claims 42-44 of the present invention recite a method of delivering medicament to tissue while preventing medicament washout. A medicament delivery catheter having a tissue engaging surface with a sealing balloon is provided. The sealing balloon is inflated to sealably engage the tissue engaging surface against a tissue surface. Flaherty et al. relates to a transvascular system for delivering drug to a tissue. The system includes a catheter having puncturing, orientation, drug delivery, and imaging elements.

Flaherty et al. describes the injection of a sealant or matrix material into a cavity created by the catheter. However, Flaherty et al. does not disclose a sealing balloon which is inflated to sealably engage a tissue engaging surface against a tissue surface in conjunction with the creation of an opening and sealing the opening with the balloon so that medicament can be delivered without washout.

The catheter of Flaherty et al. may include a balloon or expandable structure to push an osmotic surface into contact with a vessel wall to deliver medicament. However, Flaherty et al. does not teach the use of a balloon to seal an opening created by the catheter to prevent medicament washout.

The catheter of Flaherty et al. also may include a porous balloon for infusing a drug. However, a porous drug delivery balloon cannot be used as a sealing balloon by virtue of its porosity, which permits fluid to flow therethrough. Thus, in this instance Flaherty teaches away from the present invention.

The catheter of Flaherty et al. may also include stabilizing balloons to anchor the catheter. However, these are not sealing balloons which can be used in conjunction with the creation of an opening and sealing the opening with the balloon so that medicament can be delivered without washout.

Thus, the catheter described in Flaherty et al. could not be used to practice the method of the present invention and thus could not be an anticipation reference. Furthermore, there is no suggestion of a sealing balloon that could be used in conjunction with the creation of an opening and sealing the opening with the balloon so that medicament can be delivered without washout. Hence, Flaherty et al. could not be used to render obvious the present invention of claims 42-44.

Rejections under 35 U.S.C. § 103(a)

Claims 36-38 were rejected under 35 U.S.C. §103(a) as being unpatentable over Jenkins et al. in combination with Cox et al, and Kalloo et al.

To establish a prima facie case of obviousness, three basic criteria must be met by the Examiner. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine the references teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. (see MPEP §2143.03). The applicant traverses this rejection.

The Examiner asserted that Jenkins et al teach a method as claimed and cites column 1, line 20 to column 2, line 54. Applicant believes that the Examiner has misconstrued the reference. Jenkins et al. relates to a device that is used to create circumferential lesions around the pulmonary vein and other bodily orifices. These are used to disrupt the electrical propagation within the atria so as to treat atrial fibrillation and atrial flutter. Jenkins et al. does not teach a method of medicament delivery. Cox et al. teaches the use of conventional purse-string sutures to form a hemostatic seal to inhibit blood loss during a surgical procedure. As asserted by the Examiner, Kaloo et al. teaches the use of dual stabilizing balloons to aid in the placement of a device.

The Examiner states:

"It would have been obvious to the artisan of ordinary skill, in order to wedge the probes in the method of Jenkins et al., to employ the balloons of Kaloo et al., since this would both stabilize the devices as well as seal the opening, which is desirable, since this prevents bleeding when the procedure is performed on a beating heart, as taught by Cox et al, thus producing a device and method as claimed." (See page 5 of the office action)

First, the Examiner has used the method of the present invention as a road map to attempt a hindsight reconstruction of the present invention. This is clearly impermissible. However, the Examiner has not even succeeded with his hindsight reconstruction because he has failed to cobble together all of the claimed elements.

The Examiner has failed to make a prima facie case of obviousness for the following reasons. The present invention of claims 36-38 relate to a method of delivering medicament while sealably traversing the atrial septum. The claimed method includes traversing the right atrium, puncturing the atrial septum, sealing the opening to the septum while advancing the medicament delivery catheter, creating a channel in the chamber of the heart, and delivering medicament to the channel created.

Jenkins et al. relates to a device to create lesions. Cox et al. relates to surgical systems and methods for ablating heat tissue. Cox et al. teaches purse-string sutures to prevent blood leakage during the surgical procedure. Kaloo et al. relates to the placement of a surgical device. None of the cited references deal with the peculiarities of the anatomy to which the present invention is directed. Thus, there would be no motivation to look to these references to solve the problem addressed by the present invention. Furthermore, none of the cited references relate to drug or medicament delivery. Thus, even if one looked to these references, they could not be combined to teach or suggest all of the claim limitations. For the foregoing reasons, the present invention of claims 36-38 are patentable over the cited references.

Claim 45 was rejected under 35 U.S.C. §103(a) as being unpatentable over Jenkins et al. in combination with Cox et al, and Kalloo et al. as applied to claims 36-38 and further in view of Alt. Applicant traverses the rejection. However, in the interests of expediting prosecution the applicant has canceled claim 45 without prejudice to resubmitting the claim, or claims of similar scope, in a continuation application.

Claims 39 and 40 were rejected under 35 U.S.C. §103(a) as being unpatentable over Mueller '523 in combination with Jenkins et al. Applicant believes that the Examiner intended to cite U.S. Patent No. 6,565,528 ("Mueller '528") which was cited in an earlier office action since there is no Mueller patent ending in '523 that is of record in this case.

The Examiner has asserted that Mueller '523 teaches sealing to the cardiac tissue using a vacuum port before creating a channel in the tissue and that Jenkins et al. teaches injecting drugs into channels created in the myocardium. Applicant believes that the Examiner has misconstrued both references.

Mueller '528 does not teach the use of vacuum. In one embodiment, shown in FIG. 10, a corkscrew shaped tissue-penetrating implement is rotated into tissue and then withdrawn backward creating a seal. This is not the same as activating a vacuum force through a tissue stabilizer port. Furthermore, contrary to the Examiner's assertion, Jenkins et al., does not teach injecting drugs into channels created in the myocardium. As discussed above, Jenkins et al. does not relate to drug or medicament delivery. Jenkins et al. relates to a device that is used to create circumferential lesions around the pulmonary vein and other bodily orifices. Thus, these references are not combinable to yield the present invention.

Claim 41 was rejected under 35 U.S.C. §103(a) as being unpatentable over Mueller '523 in combination with Jenkins et al. as applied to claims 39 and 40 and further in view of Jeevanandam et al. As discussed above, Mueller and Jenkins et al. are not combinable to yield the invention of claims 39 and 40. Thus, they likewise could

not yield the invention of dependent claim 41, either alone or in combination with Jeevanandam et al.

In view of the foregoing, it is submitted that claims 36-44 are in condition for immediate allowance, and such action is respectfully requested. However, if for any reason direct communication with the Applicant's attorney would serve to advance prosecution of this case to finale, the Examiner is cordially urged to call the undersigned attorney at the below listed telephone number.

Respectfully submitted,

March 27, 2006

A handwritten signature in cursive script, appearing to read "Bruce M. Canter", written over a horizontal line.

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